REMARKS/ARGUMENTS

Claims 1-88 were pending in the present application before the February 10, 2005 Office Action, which indicated that claim 1-16 were under consideration and claims 17-88 were withdrawn from further consideration as "being drawn to a nonelected invention." By this Amendment, claims 1 and 13 are amended.

The February 10, 2005 Office Action rejected claims 1-9 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Pat. No. 6,432,680 issued to Lin et al. (hereinafter "the '680 patent") in view of WO 03/002598 by Crisanti (hereinafter "Crisanti"). Moreover, claims 1-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,248,558 to Lin et al. (hereinafter "the '558 patent") in view of Crisanti.

Applicants appreciate the Primary Examiner, Dr. Swartz's careful review of the application.

In response, as set forth above, claims 1 and 13 have been amended. Support for the amendment set forth above can be found in the disclosure as originally filed at least in claims 1-88 and the specification. Thus, no new matter is added. However, the claims are not limited to the disclosed embodiments.

The following remarks herein are considered to be responsive thereto.

Double Patenting Rejections

Claims 1-9 and 13 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of the '680 patent in view of Crisanti.

Amended Claim 1

As amended, claim 1 recites "[a]n isolated fusion protein comprising: (a) a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro), and (b) an IκB protein ***that has optimal permeability through a cell membrane.***" (Emphasis added.)

In contrast, while as noticed by the Primary Examiner, claims 1-12 of U.S. Pat. No. 6,432,680 are drawn to an isolated fusion polypeptide comprising "at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro)," and "a target peptide or a target polypeptide membrane-translocating sequence," which ***teaches away*** from the present invention at least because as defined in the '680 patent, "[a] target protein is a protein which normally evidences ***less than optimal permeability*** through the cell membrane" (col. 6, lines 42-44), but IκB protein as required in claim 1 of the present application is one of the proteins that ***have optimal permeability*** through the cell membrane as identified by Crisanti (page 23, lines 6-9).

In other words, as set forth above, since it is understood that the claims 1-12 of U.S. Pat. No. 6,432,680 teach an isolated fusion polypeptide comprising "at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro)," and "a target peptide or a target polypeptide membrane-translocating sequence" that normally evidences ***less than optimal permeability*** through the cell membrane, there is ***no motivation*** to combine "a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro)" with an IκB protein that ***has optimal permeability*** through the cell membrane. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)." MPEP 2143.01 (emphasis original).

Therefore, neither the '680 patent nor Crisanti, taken alone or in combination, suggest or teach an isolated fusion protein that requires "(a) a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro), and (b) an IκB protein that ***has optimal permeability*** through a cell membrane." (Emphasis added.)

For at least the foregoing reasons, independent claim 1, as amended, is patentably distinct over the cited references.

Accordingly, claims 2-9, which depend from now allowable amended claim 1, are patentably distinct over the cited references at least for this reason.

Amended Claim 13

As amended, claim 13 recites "[a] pharmaceutical composition comprising: (a) an isolated fusion protein having: (1) a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-L- eu-Leu-Ala-Ala-Pro), and (2) an IκB protein ***that has optimal permeability through a cell membrane***; and (b) a pharmaceutically acceptable carrier." (Emphasis added.)

Incorporating herein reasons set forth above why independent claim 1, as amended, is patentably distinct over the cited references, independent claim 13, as amended, is patentably distinct over the cited references at least because neither the '680 patent nor Crisanti, taken alone or in combination, suggest or teach a pharmaceutical composition that requires "(a) an isolated fusion protein having: (1) a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-L- eu-Leu-Ala-Ala-Pro), and (2) an IκB protein ***that has optimal permeability through a cell membrane***; and (b) a pharmaceutically acceptable carrier." (Emphasis added.)

For at least the foregoing reasons, independent claims 1 and 13, as amended, are patentably distinct over the cited references. Applicants therefore respectably request the Primary Examiner to withdraw the double patenting rejection.

35 U.S.C. §103(a) Rejections

Claims 1-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over the '558 patent to Lin et al. in view of Crisanti.

Applicants respectfully traverse the rejections made by the Examiner at least for the reasons discussed below.

Amended Claim 1

As amended, claim 1 recites "[a]n isolated fusion protein comprising: (a) a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro), and (b) an IκB protein ***that has optimal permeability through a cell membrane.***" (Emphasis added.)

In contrast, as asserted by the Primary Examiner, the '558 patent issued to Lin et al. teaches an isolated fusion protein comprising a membrane-translocating sequence comprising "at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro)," and "a target peptide or a target polypeptide membrane-translocating sequence," which ***teaches away*** from the present invention at least because as defined in the '558 patent, "[a] target protein is a protein which normally evidences ***less than optimal permeability*** through the cell membrane" (col. 6, lines 42-44), but IκB protein as required in amended claim 1 of the present application is one of the proteins that ***have optimal permeability*** through the cell membrane as identified by Crisanti (page 23, lines 6-9).

Therefore, there is ***no motivation*** to combine "a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro)" with an IκB protein that ***has optimal permeability*** through the cell membrane as the Primary Examiner suggested. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)." MPEP 2143.01.

Accordingly, neither the '558 patent nor Crisanti, taken alone or in combination, suggest or teach an isolated fusion protein that requires "(a) a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro), and (b) an IκB protein that ***has optimal permeability*** through a cell membrane." (Emphasis added.)

For at least the foregoing reasons, independent claim 1, as amended, is patentably distinct over the cited references.

Accordingly, claims 2-12, which depend from now allowable amended claim 1, are patentably distinct over the cited references at least for this reason.

Amended Claim 13

As amended, claim 13 recites "[a] pharmaceutical composition comprising: (a) an isolated fusion protein having: (1) a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-L- eu-Leu-Ala-Ala-Pro), and (2) an IκB protein ***that has optimal permeability through a cell membrane***; and (b) a pharmaceutically acceptable carrier." (Emphasis added.)

Incorporating herein reasons set forth above why independent claim 1, as amended, is patentably distinct over the cited references, independent claim 13, as amended, is patentably distinct over the cited references at least because neither the '558 patent nor Crisanti, taken alone or in combination, suggest or teach a pharmaceutical composition that requires "(a) an isolated fusion protein having: (1) a membrane-translocating sequence comprising at least eight consecutive residues of SEQ ID NO: 1 (Ala-Ala-Val-Leu-Leu-Pro-Val-L- eu-Leu-Ala-Ala-Pro), and (2) an IκB protein ***that has optimal permeability through a cell membrane***; and (b) a pharmaceutically acceptable carrier." (Emphasis added.)

For at least the foregoing reasons, independent claim 13, as amended, is patentably distinct over the cited references.

Accordingly, claims 14-16, which depend from now allowable amended claim 13, are patentably distinct over the cited references at least for this reason.

CONCLUSION

Applicants respectfully submit that the foregoing Amendment and Response place this application in condition for allowance. If the Examiner believes that there are any issues that can be resolved by a telephone conference, or that there are any informalities that can be corrected by an Examiner's amendment, please call the undersigned at 404.495.3678.

Respectfully submitted,
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